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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,858	02/18/2005	Sadanobu Shirai	2005_0152A	3564

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EXAMINER	
AHMED, HASAN SYED	
ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
01/13/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/524,858	SHIRAI ET AL.	
	Examiner	Art Unit	
	HASAN S. AHMED	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants' remarks, filed on 18 October 2010.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,254,348 ("Hoffmann") (cited in the IDS of 18 May 2005) in view of U.S. Patent No. 5,866,157 ("Higo") (cited in the PTO-892 of 14 July 2006), further in view of U.S. Patent No. 5,312,627 ("Stroppolo").

Independent claim 1 recites a patch prepared by laminating an adhesive layer consisting of a rubber, an adhesive resin other than an acrylic adhesive, a plasticizer, 1 to 4 w/w % of tulobuterol as an active ingredient and 0.1 to 3 w/w % of a higher fatty acid as a drug-release controlling agent on a backing.

Hoffmann teaches a transdermal therapeutic system comprising tulobuterol (reading on the tulobuterol of claim 1) in a matrix containing at least one polystyrene-1,3-diene-polystyrene block copolymer (reading on the rubber of claim 1) (see col. 2, lines 55-58) on a backing layer (reading on the backing of claim 1) (see col. 3, line 2). The adhesive matrix may further contain aliphatic hydrocarbon resins (reading on the

adhesive resins of claims 1, 2, and 4) (see col. 3, line 41), and glycerol, (reading on the plasticizer of claims 1 and 2) (see col. 3, line 62).

Acrylic adhesives are not required by the Hoffmann invention and are not disclosed in any of the examples.

Hoffmann explains that the disclosed invention is beneficial in that it provides safe dosage of active substance with optimal release rate and tolerance (see col. 2, lines 51-52).

Example 2 of Hoffmann discloses 2% tulobuterol and Example 5 discloses 2.5% tulobuterol, both overlapping with the concentration range recited in claim 1. Example 2 discloses 22% adhesive (copolymers of diolefins and olefins), Example 2a discloses 57% adhesive, and Example 5 discloses 48% adhesive, all overlapping with the concentration range recited in claim 2. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

Example 2a discloses 38% rubber (styrene-isoprene-styrene block copolymer). A prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). *See* MPEP 2144.05.

While Hoffman teaches the use of fatty acids in the disclosed composition (see col. 3, lines 58-59), the reference does not explicitly disclose higher fatty acids.

Higo teaches a percutaneous patch formulation for releasing, *inter alia*, tulobuterol (see col. 3, lines 39 and 58). Higo does not require acrylic adhesives and does not disclose them in any of the examples. Higo teaches an adhesive layer comprising, tulobuterol at a concentration of 1-4% (see col. 3, lines 39 and 58), C_{11-22} fatty acids at a concentration of 0.01-20% (see col. 4, line 64 and col. 5, line 24), and rubber at a concentration of 15-60% (see col. 3, line 64 – col. 4, line 9), which overlap with the concentrations recited in claims 1 and 2. It would have been obvious to a person of ordinary skill in the art to modify the teachings of Hoffman with the teachings of Higo to arrive at C_{11-22} fatty acids at a concentration of 0.01-20% since both references teach transdermal formulations comprising, *inter alia*, a low concentration of tulobuterol and fatty acids.

Hoffmann does not disclose percentages for plasticizers, however it is the position of the Examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue

from the instant percentage ranges. Plasticizer concentrations overlapping with those being claimed are recognized by the art as result effective variables. Higo teaches plasticizers at a concentration of 10-60% (see col. 4, line 52). Stroppolo teaches plasticizers (e.g. polyethylene glycols) at a concentration of 4-20% (see col. 4, line 53). Stroppolo teaches a transdermal therapeutic system for releasing, *inter alia*, tulobuterol (see col. 4, line 35). Stroppolo does not require acrylic adhesives and does not disclose them in any of the examples.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to prepare a patch consisting of a rubber, an adhesive resin other than an acrylic adhesive, a plasticizer, tulobuterol, and a higher fatty acid, as taught by Hoffmann in view of Higo, further in view of Stroppolo. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it provides safe dosage of active substance with optimal release rate and tolerance, as explained by Hoffmann (see above).

* * * * *

Response to Arguments

Applicants' arguments filed on 18 October 2010 have been fully considered but they are not persuasive.

Applicants argue that Hoffman does not disclose higher fatty acids as a release controlling agent for tulobuterol. See remarks, page 2.

Regarding the teaching of higher fatty acids, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of

references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Examiner respectfully submits that the Higo reference was invoked for the teaching of higher fatty acids in an adhesive patch preparation comprising tulobuterol. Regarding higher fatty acids as release controlling agents, Higo teaches the higher fatty acids being claimed instantly (see col. 4, line 64 and col. 5, line 24). "'Products of identical chemical composition can not have mutually exclusive properties.' A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)." *See* MPEP 2112.01.

Applicants argue that solubilizers and plasticizers, including fatty acids, mineral oil, glycerol, and paraffins are taught generally by Hoffman, but not used in an example and are neither essential nor important for the invention of Hoffmann. See remarks, page 2.

The applicants' arguments are based on what the examiner believes to be a narrow interpretation of the prior art. Examiner respectfully submits that a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including non-preferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). It is the position of the examiner that one of ordinary skill in the art, given both the prior art and the claims in their present form their broadest reasonable

interpretation, would find the claimed invention obvious in view of the prior art. See MPEP § 2111 and 2123.

Applicants argue that Higo requires both an organic acid and an absorption enhancer. See remarks, page 3.

Examiner respectfully submits that the claimed higher fatty acid fits the definition of both organic acid (see col. 2, lines 56-61) and absorption enhancer (see col. 4, line 64 and col. 5, line 24).

Applicants argue that higher fatty acids are illustrated as one of many absorption enhancers and are not preferred or used in working examples. See remarks, page 3.

As indicated above, examiner respectfully submits that a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including non-preferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989).

Applicants cite comparative example 6 of the instant specification to show that an absorption enhancer disclosed by Higo, i.e. isopropyl myristate, demonstrates a lower drug permeation rate compared to the instantly claimed patch. See remarks, page 4 and paragraph bridging pages 5-6.

Examiner respectfully submits that isopropyl myristate is an optional absorption enhancer disclosed by Higo. As noted in the substantive rejection, Higo also discloses the higher fatty acids being claimed instantly (see col. 4, line 64 and col. 5, line 24).

Applicants argue that the statement from the Office action that "Higo does not require acrylic adhesives" should be withdrawn because Higo teaches that, "a tackifying

resin, glycerin esters of rosin are most preferable...As the hydrophobic high molecular material, acrylic polymer may be exemplified..." See remarks, page 4.

Examiner respectfully submits that applicants have not shown that Higo requires acrylic adhesives. The portions of Higo cited show that acrylic adhesives may be preferred (i.e. optional), not required.

Applicants argue that comparative example 4, containing no higher fatty acid, shows an unexpected effect. See remarks, page 6.

Again, examiner respectfully submits that Higo discloses the higher fatty acids being claimed instantly (see col. 4, line 64 and col. 5, line 24).

Applicants argue that the subject matter of the instant invention is completely different from Hoffman's invention. See remarks, page 6.

Examiner respectfully submits that any difference in objectives does not defeat the case for obviousness because, as MPEP § 2144 states, the "reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) ...; In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991) ... .".

Applicants argue that the transition phrase "consisting of" excludes Higo's combination of organic acid and absorption enhancer. See remarks, page 6.

As indicated above, examiner respectfully submits that the instantly claimed limitations related to higher fatty acids fall within Higo's definition of both an organic acid (see col. 2, lines 56-61) and absorption enhancer (see col. 4, line 64 and col. 5, line 24).

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

*

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615